

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

Application of:

Examiner: Michener, Jennifer Kolb

Pacetti et al.

Serial No.: 10/040,538

Art Unit: 1762

Filed: 12/28/01

Title: A System and Method for Coating Implantable Devices

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Declaration under 37 CFR § 1.132

I, Syed Hossainy, declare the following:

1. I earned a BS degree in Chemical Engineering from Bangladesh University of Engineering and Technology in 1988 and a PhD from University of Texas in 1992.
2. I am currently employed by Abbott Corporation as a Director of Research and Development.
3. I am currently a Research Affiliate with Harvard-MIT Biomedical Engineering Center and am in collaboration with Dr. Elazer Edelman's lab in the area of cardiovascular implant and local pharmacokinetics.
4. I was a Fellow Director of Research and Development at Guidant Corporation from 2003 to 2006.

5. As a Fellow Director at Guidant Corporation my responsibilities included development of biomaterial strategy for controlled drug release technology; development of strategy for new medical device technology platforms; and development of controlled release technology for combination drug-device application, specifically drug eluting stents.
6. I was an Advisor at Guidant Corporation, Vascular Intervention Group from 2000 to 2003.
7. As an Advisor at Guidant Corporation my responsibilities included development of controlled release technology for local therapeutic effects, including for drug delivery stents; and selection of implantable biomaterials for drug delivery stent coatings and other cardiovascular devices.
8. I was a Principal Scientist and Project Leader at Guidant Corporation, Vascular Intervention Group from 1999 to 2000.
9. As a Principle Scientist and Project Leader my responsibilities included development of drug delivery stent technology.
10. I was a Senior Scientist and Project Group Leader at Johnson and Johnson Corporation (J&J) from 1996 to 1999.
11. At J&J, my responsibilities included development of anti-restenosis coronary stents; design of nonthrombogenic biomaterial surfaces; design of small diameter vascular graft surface; application of photocurable absorbable polymer in drug-delivery; enhancement of filler-matrix interfacial strength in composite biomaterial; processing of different I.V. absorbable polymers by

solution spinning; processing of different polymers by electrostatic spinning; and synthesizing and characterizing of novel antithrombogenic absorbable polymer.

12. I was a Senior Scientist at J&J Medical Inc. from 1995 to 1996.

13. At J&J Medical Inc. my responsibilities included preparation of antimicrobial drug delivery indwelling catheters and development of surface modification for antithrombogenicity and anticalcification.

14. I am an inventor of U.S. Patent No. 6,395,326 assigned to Advanced Cardiovascular Systems Inc., which was a subsidiary of Guidant Corporation.

15. U.S. Patent No. 6,395,326 is now owned by Abbott Corporation.

16. I have read and understand the content of U.S. Patent No. 6,395,326.

17. I have read and understand the contents of Application Serial No. 10/040,538 assigned to Advanced Cardiovascular Systems Inc., now owned by Abbott Corporation.

18. I submit that U.S. Patent No. 6,395,326 does not teach "directing a gas, from a gas dispenser positioned at a distance from the coating dispenser, onto the implantable medical device, wherein if the solvent has a vapor pressure greater than 17.54 Torr at ambient temperature the temperature of the gas is adjusted to decrease the evaporation rate of the solvent, and if the solvent has a vapor pressure of less than 17.54 Torr at ambient temperature the temperature of

the gas is adjusted to increase the evaporation rate of the solvent,” as recited by claim 1 of Application Serial No. 10/040,538.

19. I submit that U.S. Patent No. 6,395,326 does not teach “blowing a gas, from a gas blower positioned at a distance from the coating dispenser, directly onto the implantable medical device to either increase or decrease the evaporation rate of the solvent from the composition on the implantable medical device, wherein if the solvent is non-volatile the temperature of the gas is adjusted to increase the evaporation rate of the solvent, and if the solvent is volatile the temperature of the gas is adjusted to decrease the evaporation rate of the solvent,” as recited by claim 23 of Application Serial No. 10/040,538.

20. I submit that U.S. Patent No. 6,395,326 does not teach “blowing a gas from a blower onto the stent to either increase or decrease the evaporation rate of the solvent from the coating substance on the stent based on the volatile properties of the solvent; and rotating the stent supported by the support assembly about a longitudinal axis of the stent,” as recited by claim 54 Application Serial No. 10/040,538.

21. I believe that U.S. Patent No. 6,395,326 fails to teach what is recited in the independent claims of the above-identified application.

22. I further declare that all statements made herein of our own knowledge are true and that all statements made upon information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States

Code, and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

Executed on _____

Syed Hossainy